

REMARKS/ARGUMENTS

The foregoing amendments to the claims are of a formal nature, and do not add new matter. Claims 119-138 were pending in this application and were rejected on various grounds. Claims 127-128 are canceled without prejudice or disclaimer. Claims 119-123 have been amended to recite "wherein the polypeptide encoded by said nucleic acid induces chondrocyte proliferation." Claims 132-134 have been amended to recite the hybridization conditions used in the invention. The rejections to the presently pending claims are respectfully traversed.

Priority

Applicants rely on the chondrocyte proliferation assay for patentable utility which was first disclosed in International Application PCT/US00/08439, filed March 30, 2000, priority to which has been claimed in this application. Hence, the present application is entitled to at least the priority date of **March 30, 2000**.

Information Disclosure Statement

Applicants submit an IDS separately enlisting references recited in the Blast report in order to be compliant with 37 C.F.R. § 1.98(a)(1). Consideration of this Information Disclosure Statement is respectfully requested.

Specification

A. The disclosure was objected to by the Examiner as containing "embedded hyperlink and/or other form of browser-executable code." The foregoing amendment to the specification which deleted all embedded hyperlinks, is believed to overcome the present objections.

B. The title of the invention has been amended to better describe the claimed invention.

Accordingly, Applicants believe that all objections to the specification have been overcome and should be withdrawn.

Claim Objections

The syntax of Claims 119-131 was objected to for referring to 'Figures' in the claim language. Accordingly, Applicants have amended the claims to delete such references and thus this objection should be withdrawn.

Claim Rejections – 35 U.S.C. §112, First Paragraph - Enablement

Claims 119-138 are also rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner noted that for the biological deposit ATCC 209976, Applicants need to provide a declaration containing (1) the current ATCC address; and (2) a statement stating that all restrictions imposed by the depositor on the availability of deposited material to the public will be irrevocably removed upon the granting of the patent.

Applicants submit that amendments to the specification have (1) the current ATCC address; and (2) incorporated the requisite assurances that "all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the pertinent U.S. patent." Thus, this rejection should be withdrawn.

Claims 119-138 are further rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserts that while the specification enables the nucleic acids that encode the polypeptide defined by SEQ ID NO: 344 or 345, it does not enable other variants without any functional activity. The Examiner notes that the claims are broad because they do not recite any functional activity and hence, asserts that it would require undue experimentation to use the invention commensurate in scope with the claims.

The instantly pending claims have been amended to include a functional recitation "wherein the polypeptide encoded by said nucleic acid induces chondrocyte proliferation." Applicants have further removed references to "extracellular domains". Accordingly, Applicants submit that the skilled artisan would not require undue experimentation to make and use the claimed invention.

Accordingly, Applicants request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. §112, First Paragraph - Written Description

Claims 119-138 are also rejected under 35 U.S.C. §112, first paragraph, because, according to Examiner, the subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing.

Without acquiescing to the propriety of this rejection, Applicants have amended Claims 119-124 to recite a functional recitation: "wherein the polypeptide encoded by said nucleic acid induces chondrocyte proliferation." Claims 127-128, have been canceled without prejudice or disclaimer and hence this rejection is moot with respect to these claims. Applicants respectfully traverse this rejection to the remaining pending claims.

The Legal Standard for Written Description

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph, is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *In re Kaslow*, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also *Vas-Cath, Inc. v. Mahurkar*, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. See e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *Union Oil v. Atlantic Richfield Co.*, 208 F. 3d 989, 996 (Fed. Cir. 2000).

Arguments

As noted above, whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. The instant invention, defined by the claims, concerns

polypeptides having 80%, 85%, 90%, 95% or 99% sequence identity with the disclosed nucleic acids encoding the polypeptide sequence SEQ ID NO: 344 and further, with the functional recitation: "wherein the polypeptide encoded by said nucleic acid induces chondrocyte proliferation." Based on the detailed description of the cloning and expression of variants of PRO844 in the specification, the description of the chondrocyte proliferation assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequence SEQ ID NO: 344 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know that Applicants possessed the invention as claimed in the instant claims.

Hence, Applicants submit that this rejection should be withdrawn.

Claim Rejections – 35 U.S.C. §112, Second Paragraph

Claims 119-138 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite.

A. The Examiner alleges that the protein identified as PRO844 is disclosed as a soluble protein (protease) and accordingly, claims that recite an "extracellular domain" is indefinite as the art does not recognize soluble proteins as having such domains.

Without acquiescing to the propriety of this rejection, merely to expedite prosecution in this case, Applicants have deleted any reference to "extracellular domains" in the pending claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

B. Claims 132-134 were rejected as vague and indefinite for reciting the term "hybridizes" without reciting any conditions or reciting "stringent conditions" wherein these conditions are not known.

Without acquiescing to the propriety of this rejection, merely to expedite prosecution in this case, Applicants have added the precise hybridization conditions to Claims 132-134. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. §102

Claims 119-138 were rejected under 35 U.S.C. §102(b) as being anticipated by Ni *et al.* (U.S.P.N. 6566478) dated 2003.

As discussed above, Applicants rely on the chondrocyte proliferation assay for patentable utility and are at least entitled to a priority date of **March 30, 2000**. Accordingly, Ni *et al.* (U.S.P.N. 6566478) dated 2003 is not prior art and hence, this rejection should be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641**, referencing Attorney's Docket No. **39780-2730 P1C61**).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: August 6, 2004

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